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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,448	10/27/2003	Kathleen C.M. Campbell	SIU 7398	8896

321 7590 01/19/2007

SENNIGER POWERS
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER	
GRAFFEO, MICHEL	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	01/19/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/19/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary	Application No.	Applicant(s)	
	10/694,448	CAMPBELL, KATHLEEN C.M.	
	Examiner	Art Unit	
	Michel Graffeo	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-33,35,36 and 38-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7-33,35,36 and 38-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *23 Oct 06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Action

Claims 1, 3-5, 7-33, 35-36 and 38-45 are examined.

Applicant has amended claims 1 and 32 and provided arguments for the patentability of claims 1, 3-5, 7-33, 35-36 and 38-45 in the response filed 21 August 2006.

Applicant's arguments, see response, filed 21 August 2006, have been fully considered but are not persuasive. Additionally, upon further consideration, a new ground(s) of rejection is made. As previously recited in the prior Office Action, all other rejections have been maintained. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 August 2006 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-4, 8, 17-25, 30-33 and 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Deegan et al. The nephrotoxicity, cytotoxicity and renal handling of a cisplatin-methionine complex in male Wistar rats, Toxicology, (1994), 89:1-14.

Deegan et al. teach the administration of cisplatin:methionine wherein the administration comprises 6mg/kg of body weight and ratios of cisplatin:methionine of from 1:0 to 1:10 (see pages 9-10). The administration is taught to prevent nephrotoxicity during cancer treatment with the cisplatin chemotherapy. That the patient is being dosed for cancer with the platinum-coordination compound and dosed with L-methionine (see Materials and methods on page 3) and dosed in the same range as in the claims the claim limitations are being practiced. Since products of identical chemical composition cannot have mutually exclusive properties, a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. Further to that end, since the same amounts are dosed in the reference they must necessarily reach the claimed blood serum level as.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-5, 7-33, 35-36 and 38-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over 5,466,678 (Kowabata et al) in view of Deegan et al. The nephrotoxicity, cytotoxicity and renal handling of a cisplatin-methionine complex in male Wistar rats, Toxicology, (1994), 89:1-14 and further in view of Ormond et al. Reduced Nephrotoxicity In Vivo and In Vitro of Cisplatin-methionine Complex, Brit. J. Pharmacology (suppl)., (1998), 95:584 (both of which Deegan et al. and Ormond et al. are added only as directly corresponding evidence to support the prior common knowledge finding of Kowabata et al.).

Kowabata (column 3, line 1 through column 4, line 8, Test Example 3, claims) discloses a method of using S-adenosyl-L-methionine to reduce nephrotoxicity of a platinium complex compound using the recited orders of administration, routes of administration, dosages and ratios of otoprotective agent to platinum coordination compound. The instant claims appear to differ over Kowabata in reciting a method for preventing ototoxicity. However, it would be inherent that S-adenosyl-L-methionine would prevent ototoxicity caused by a platinium complex compound, since a patient receiving a platinium complex compound is at risk for both nephrotoxicity and ototoxicity

and using S-adenosyl-L-methionine to reduce nephrotoxicity would at the same time also prevent ototoxicity cased by the platinium complex compound. Additionally, Kowabata teach that the methionine agent can be administered prior to, simultaneously with or after the platinum compound (see col 3 lines 55-65).

Although Kowatbata do not disclose the methionine derivates of claim 35 for example, but such would be obvious over the teachings that "the present inventors have made extensive studies on SAMe, focusing attention on the fact that glutathione or the like SH-compounds produced in the living organisms detoxicate active oxygen or chemically reactive toxicants through reaction therewith. As a result, the afore-mentioned objects have now been found to be achievable in accordance with the present invention." to the extent that L-methionine (claim 35) is involved in the production of S-adenosyl-L-methionine (see, Col 2 lines 10-17). For support of such obviousness, see Deegan et al. and Ormond et al. which both teach the administration of methionine and particularly L-methionine (in Ormond et al. paragraph 2) with cisplatin to reduce nephrotoxicity of the cisplatin. Deegan et al. additionally teach the administration of 6mg/kg of body weight and ratios of cisplatin:methionine of from 1:0 to 1:10 (see pages 9-10). Since products of identical chemical composition cannot have mutually exclusive properties, a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. Further to that end, since the same amounts are dosed in the reference they must necessarily reach the claimed blood serum level as.

Kowabata further teaches that examples of the platinum complex compounds described above include cisplatin (cis-diamine-dichloro-platinum; CDDP), carboplatin, dichloro-ethylenediamine-platinum (II), 1,2-diamino-cyclohexyl-platinum (II)-malonate or sulfate, diisopropylamino-trans-dihydroxy-cis-dichloro-platinum (IV), (-)-(R)-2-aminomethylpyrrolidine (1,1-cyclobutanedicarboxylate)platinum (II)-monohydrate and cis-diamineglycolateplatinum (see col 3 lines 27-37.). Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

Response to Arguments - 35 USC § 112

Applicant's arguments filed 21 August 2006 have been fully considered but they are not persuasive.

Claims 3-5, 7-33, 35-36 and 38-45 remain rejected under 35 USC § 112 and as noted above Applicant is referred to the previous Office Action for the rejection. In response, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. It is not seen from the data in the specification that the compound of the claims can be used to treat ototoxicity. Applicant's argument regarding "treat" is not persuasive, since "treat" is understood as providing a cure or relief of an existing condition. To such extent, see Experimental treatments to prevent ototoxicity http://www.dizziness-and-balance.com/disorders/bilat/bilat_prevent.htm Retrieved 13 April 2006 which updates the awareness of preventing ototoxicity caused

by cisplatin for example by teaching that "free radical generation plays an important role in auditory toxicity from aminoglycosides, cisplatin and noise. Agents that reduce free radical formation may be protective and manipulations that increase free-radicals are harmful to hearing. Also agents that inhibit programmed cell death (apoptosis), are thought to have some promise in preventing neuronal death, although they also have a propensity to promote tumors. At this writing, there are exploratory studies done in animals which do show that these agents are protective, but the delivery method is often impractical and the risk/benefit profile of these agents in humans needs to be established." which shows that a preventative measure has not yet been established somewhat in light of the issues concerning delivery of active agents.

Response to Arguments - 35 USC § 103

Applicant's arguments filed 21 August 2006 have been fully considered but they are not persuasive. As noted above the amended claims which do not recited S-adenosyl-L-methionine have new matter issues and to the extent that the claim is being examined without such amendment the references are still applicable and teach/suggest each and every limitation of the claims. Moreover, S-adenosyl-L-methionine is still covered by claim 1 since no amendment was made thereto.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

28 December 2006
MG

Ardin H. Marschel 1/5/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER